

elements more important to assessing value may improve these processes and contribute to giving a fairer access to appropriate treatments to patients.

PCN336**TRENDS IN END-OF-LIFE APPRAISALS AND RECOMMENDATIONS BY NICE FOR ONCOLOGY THERAPIES**

Banerjee P, Kapoor A, Mazumder D, Saxena D, Raj R
Optum Global Solutions, Noida, India

OBJECTIVES: The end-of-life consideration introduced by NICE in January 2009 allows extension of the upper limit of the cost-effectiveness thresholds beyond £30,000 per QALY for therapies that are indicated in patients with a short life expectancy and for small patient populations, with survival benefit of at least 3 months. The aim of this study was to assess the impact of the end-of-life considerations on health technology assessment (HTA) recommendations for oncology therapies. **METHODS:** NICE single technology appraisals (STAs) for oncology therapies published between 2009 and June 11, 2015 were assessed. End-of-life consideration, HTA recommendations, incremental cost-effectiveness ratio (ICER) values and the availability of patient access schemes were extracted. **RESULTS:** A total of 53 STAs were identified during the study period and 20 appraisals/therapies met the end-of-life criteria. Maximum end-of-life considerations were granted in the year 2009 and 2012 (4 each), while 2013 to 2015 recorded the minimum (2 each). Of the therapies meeting the end-of-life criteria, 13 received positive recommendations with the ICER values ranging from £31,800 to £58,590. Highest percentage of positive recommendations were reported in the year 2009 (100%), whereas no positive recommendations were recorded in 2013, which could be attributable to the high ICER values of the end-of-life therapies appraised in 2013 (£40,000 to £100,000). In 2014 and 2015 each, 50% therapies (1/2) received positive recommendations. Of the 13 positive recommendations, 11 included patient access schemes by manufacturers. Unacceptably high ICER values followed by economic modelling issues leading to uncertain ICER values were major drivers of negative decisions. **CONCLUSIONS:** The use of end-of-life criteria for maximizing patient access remains suboptimal, as fewer treatments have met the end-of-life criteria in recent years. Also, increasing ICER values in end-of-life cancer appraisals have resulted in negative decisions. Patient access schemes by manufacturers may improve patients' access to novel end-of-life oncology therapies.

PCN337**PAYER/HTA REQUIREMENTS IN METASTATIC BREAST CANCER**

Holmstrom S¹, Kooreman PJ², Van Engen A³, Heemstra L³, Novak A⁴, Naidoo S⁴

¹Astellas Pharma Global Development, Leiden, The Netherlands, ²Quintiles, Hoofddorp, The Netherlands, ³Quintiles Advisory Services, Hoofddorp, The Netherlands, ⁴Astellas, Chertsey, UK

OBJECTIVES: A key challenge for successful introduction of new drugs in metastatic breast cancer (MBC) is a positive health technology assessment (HTA) outcome across Europe. Thus, understanding of the MBC HTA landscape is essential. This study aims to identify key decision drivers and challenges for HTA in MBC. **METHODS:** An in-depth analysis of published HTA submissions in MBC over the last 5 years was conducted. In total, 96 HTA reports in MBC from 9 agencies were identified. Based on submission type and approval status, 38 HTA assessments for 8 drugs were selected for further analysis. The analysis focussed on the submitted data and valuation by the different agencies. Outcomes were validated in an HTA expert meeting. **RESULTS:** Of 38 HTA assessments, 11 received a negative recommendation, 8 a positive recommendation, and 13 a positive recommendation with restrictions. The remaining 6 assessments were ongoing/did not provide a recommendation as yet. The majority of submissions included RCTs with PFS as primary endpoint and OS as secondary endpoint. HRQoL was not provided in 13/38 cases, with criticism in 8/38 cases. Some criticism was expressed regarding the logistics of HRQoL collection. The weight assigned to significance and incremental PFS and OS differed between countries. Twenty-eight of 38 submissions included a PE evaluation. The key uncertainties in economic modelling related to validation of OS and PFS modelling (9/28) and the incorporation of safety data (11/28). Unfavourable ICERs and uncertainty in economic modelling were key drivers for negative decisions. **CONCLUSIONS:** Gaining favourable HTA recommendation for new MBC drugs is challenging. In order to improve probability of successful introduction of a new MBC drug, demonstrating significant and clinically meaningful incremental OS and/or PFS is key, as is providing strong HRQoL data. Moreover, well-validated PE model and acceptable ICERs are important to gain favourable HTA opinion.

PCN338**PERSONALISED BREAST SCREENING: KEY DRIVERS OF COST EFFECTIVENESS**

Gray E, Jelonek A, Payne K
University of Manchester, Manchester, UK

OBJECTIVES: This study estimates the cost-effectiveness of personalised breast cancer screening compared to one-size-fits-all screening. Personalised breast cancer screening has been proposed to both improve outcomes and screening programme efficiency. In a personalised screening programme frequency of mammography is varied based on women's estimated risk of breast cancer. The Adapting Breast Cancer Screening Strategy Using Personalised Risk Estimation (ASSURE) project is a Europe-wide programme of work investigating new technologies and strategies in personalised screening. As there is substantial uncertainty at this stage about several aspects of personalised screening the objective of this study is to provide information on which parameters are key in determining whether or not this strategy is cost-effective. **METHODS:** The structure of an economic model to assess the cost-effectiveness of personalised screening was developed with input from clinical experts. A preliminary proposal uses three risk groups with triannual, biannual and annual screening offered. The modelling technique of discrete event simulation was used to combine a natural history model of breast cancer, risk stratification procedures, screening processes and expected outcomes over a lifetime horizon. Parameters in this mathematical model were informed by previously published modelling studies and data gathered within

the ASSURE project. In this preliminary analysis, the comparative cost-effectiveness of personalised screening strategies and current practice was calculated as a cost-per-case-detected from a health service perspective. Uncertainty in the cost-effectiveness estimate is investigated using one-way sensitivity analyses of key parameters. **RESULTS:** The incremental cost-effectiveness ratio of a three risk group stratification procedure in the base case was £45,617 per-case-detected. Influential parameters were sensitivity of mammography, recall rate, cancer growth parameters and accuracy of risk estimation. **CONCLUSIONS:** A very simple stratification procedure may not be cost-effective. The optimal risk stratification for personalised breast screening will be investigated to determine whether this offers improvement in cost-effectiveness.

PCN339**ANALYSIS OF DIFFERENCES IN HTA REIMBURSEMENT DECISIONS OF STAGE IV (METASTATIC) BREAST CANCER MEDICATIONS ACROSS DIFFERENT COUNTRIES**

Schoenherr N¹, Gordon J²

¹Boehringer Ingelheim Ltd., Bracknell, UK, ²Boehringer Ingelheim GmbH, Ingelheim am Rhein, Germany

OBJECTIVES: Besides being associated with a negative impact on patients' lives and a low 5-year survival rate[1], stage IV (metastatic) breast cancer is accompanied with high treatment costs. The objective of this research was to analyse recent HTA decisions on metastatic breast cancer of different national HTA bodies worldwide and investigate reasons for variances in their decision making. **METHODS:** Reimbursement decisions for metastatic breast cancer treatments across various national HTA bodies published between January 2013 and May 2015 were analysed. Factors such as variations in treatment guidelines, different disease mutations, specific lines of therapy or if the drug was a single or add-on treatment were not considered. Each HTA decision was analysed according to the following criteria: clinical value, survival benefit, price, ICER (where applicable), toxicity and quality of life. Treatments were not compared with each other, but the HTA evaluation of each treatment was considered across the single countries. **RESULTS:** A review of 5 breast cancer medications recently assessed independently across 9 HTA authorities (6 European HTA bodies, Canada, Australia, Japan) showed that generally, drugs with sufficient proof of clinical value were nationally reimbursed. Positive reimbursement decisions for all treatments were made in Germany and France, while NICE and SMC only gave negative opinions. Most common reasons for non-approvals or restrictions were "lack of cost effectiveness" and "lack of clinical value" in respectively 10 and 3 of the HTA submissions. **CONCLUSIONS:** HTA decisions for metastatic breast cancer treatments differ across countries, with some appearing to be more willing to reimburse medications. Clinical effectiveness was the most important decision factor for 5 countries, whereas cost-effectiveness was more relevant to the remaining 4 HTA bodies. With novel medications for metastatic breast cancer coming to market in the next years[2], certain criteria for HTA assessments might need to be re-defined. [1] <http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-survival-by-stage> [2] <http://www5.komen.org/BreastCancer/EmergingMetastaticBreastCancer.html>

PCN340**TO WHAT EXTENT DO PAYERS' ASSESSMENT OF CLINICALLY RELEVANT OUTCOMES ALIGN WITH CLINICIANS IN ONCOLOGY?**

Ryan J¹, van Engen A², Heemstra L³, Kreeftmeijer J³

¹AstraZeneca, Cambridge, UK, ²Quintiles, Hoofddorp, The Netherlands, ³Quintiles Advisory Services, Hoofddorp, The Netherlands

OBJECTIVES: Payers are seeking improvements in outcomes that are meaningful for the patient, but the preference of payers on what change can be considered meaningful is not well defined. Clinically relevant differences (CRDs) in outcomes and grading of their magnitude in oncology are being established by both European and American oncology organisations (European Society for Medical Oncology (ESMO) and American Society of Clinical Oncology (ASCO)). This indicates a transition from a focus primarily on statistical significant improvements (i.e., "is there a difference?") in outcomes towards the clinical relevance of these improvements (i.e., "does the difference matter to patients?"). The attitude of payers towards CRDs in oncology outcomes is not well-understood, with little guidance around oncology CRDs from payers. The objective of this study is to evaluate the alignment between payers and clinicians in their assessment of clinical and health benefit of oncology products. **METHODS:** Oncology products launched recently were evaluated using the approach suggested by ESMO and ASCO. For the same products, the payer decision was evaluated to establish the clinical and health benefit rating by NICE (UK), HAS (France) and G-BA (Germany). **RESULTS:** Not all products granted market approval have been evaluated by payers. The research showed that where they had been evaluated, payer quantification of clinical benefit differed to that recommended by oncology societies. Furthermore, clinical benefit assessment, particularly regarding overall survival improvement, differed between payers themselves. **CONCLUSIONS:** Oncology societies are recognising the need to ensure consistent assessment and representation of clinical benefit of new oncology products. Whilst payers often have guidance on how they assess benefit, this is often generic and applied across therapy areas. As a consequence, there still remains an inconsistent approach to evaluating clinical benefits in oncology between payers, which provides challenges and implications in drug development programmes for novel oncology therapies.

PCN342**RELATIONSHIP BETWEEN THE PREVALENCE OF CANCERS IN ENGLAND AND WALES AND THE PERFORMANCE OF TECHNOLOGY APPRAISALS**

Hughes R¹, Chawla R²

¹AccuScript Consultancy, Reading, UK, ²AccuScript Solutions, Ludhiana, India

OBJECTIVES: Cancer is the most common cause of mortality in England and Wales. This study investigated whether the number of technologies assessed by NICE for a specific cancer reflects its prevalence in England and Wales **METHODS:** 1-year